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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,121	08/10/2001	Daniel P. Gold	032077.0003.UTL	4259

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EXAMINER	
ROARK, JESSICA H	

ART UNIT	PAPER NUMBER
1644	13

DATE MAILED: 03/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,121	GOLD ET AL.	
	Examiner	Art Unit	
	Jessica H. Roark	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2002 and 14 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-60 are pending.

2. Applicant's Status Inquiry, filed 11/18/02 is acknowledged. This Office Action should serve in response to said inquiry.

3. Applicant's preliminary amendment, filed 11/5/01 and received 1/14/02, is acknowledged. However, the amendment has not been entered because a clean copy of Table 3 was not provided in accordance with 37 CFR 1.121. In addition, although the amendment indicates that a marked-up copy was filed, this copy was not found as part of the amendment in the file.

Applicant should re-submit the requested change to Table 3.

4. Applicant is reminded to amend the Brief Description of the Drawings to reflect the numbering used in the Figures and to describe each individual panel.

For example, "Figure 3:" should read -- Figures 3A-3C: --. In addition, a description should be provided for each panel.

Appropriate correction is required.

Sequence Compliance

5. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

6. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-33, drawn to a method of altering a B cell mediated pathology by administering a chimeric protein, classified in Class 514, subclass 885 and Class 424, subclass 133.1.

II. Claims 34-51, drawn to composition comprising a chimeric protein; classified in Class 424, subclass 133.1.

III. Claims 52-60, drawn to vectors comprising portions of a chimeric protein; classified in Class 435, subclass 320.1.

The Inventions are distinct, each from the other because:

7. Groups II and I are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the composition comprising a chimeric protein of Group II can be used for identifying or purifying the protein recognized by the chimeric protein, or can be used as an immunogen to produce an anti-idiotypic antibody to the chimeric protein.

In addition, other compositions can be used to alter a B cell mediated pathology in a patient, for example compositions comprising anti-B cells antibodies or methylprednisolone.

8. Groups II and III are different products. Vectors and compositions comprising a chimeric protein differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.

9. Groups III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.

10. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the particular method of use. Moreover, a prior art search also requires a literature search, which would not be completely co-extensive. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

11. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II: wherein the chimeric protein comprises:

A) a portion of a VH region linked to a portion of a constant region without a portion of a VL region linked to a portion of a constant region,

B) a portion of a VL region linked to a portion of a constant region without a portion of a VH region linked to a portion of a constant region, or

C) both a portion of a VH region linked to a portion of a constant region and a portion of a VL region linked to a portion of a constant region.

Chimeric proteins comprising only a VH, only a VL, or a VH+VL each differ in structure and physiological properties; therefore each form of chimeric protein represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 generic.

12. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II: wherein the portion of the immunoglobulin VH constant region is:

A) human IgG1,
B) human IgG2,
C) human IgG3,
D) human IgG4,
E) human IgA1,
F) human IgA2,
G) human IgM,
H) human IgD, or
I) human IgE.

Each VH constant region differs in structure and physiological properties; therefore each represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 generic.

13. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II: wherein the portion of the immunoglobulin VL constant region is:

A) a human kappa constant region, or
B) a human lambda constant region.

Each VL constant region differs in structure and physiological properties; therefore each represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 generic.

14. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II: wherein the composition:

A) does not further comprise a carrier protein, a cytokine or a chemokine;
B) further comprises a carrier protein, but not a cytokine or a chemokine;
C) further comprises a cytokine, but not a carrier protein or a chemokine;
D) further comprises a chemokine, but not a carrier protein or a cytokine;
E) further comprises both a carrier protein and a cytokine, but not a chemokine;
F) further comprises both a carrier protein and a chemokine, but not a cytokine;
G) further comprises a cytokine and a chemokine, but not a carrier protein; or
H) further comprises a carrier protein, a cytokine and a chemokine.

Each composition differs in its individual components and has different physiological properties; therefore each composition represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 generic.

15. This application contains claims directed to the following patentably distinct species of the claimed invention I: wherein the chimeric protein can be isolated using::

A) protein A,
B) protein G, or
C) protein L.

Protein A, protein G and protein L differ in their structures and with respect to which immunoglobulin constant regions each protein binds; therefore each represents patentably distinct subject matter.

An election of the protein used to isolate the chimeric protein must be consonant with the constant region elected supra.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic.

16. This application contains claims directed to the following patentably distinct species of the claimed inventions I and II: wherein the B cell mediated pathology is one of the B cell mediated pathologies set forth in claims 48, 49 or 51. *Please note that "B cell lymphoma" (e.g., claims 32 and 47) is not a species, but will be encompassed by an election of the specific forms of B cell lymphoma set forth in claims 48 and 49.*

Each B cell mediated pathology differs with respect to its pathophysiology and patient population; therefore each represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 34 generic.

17. This application contains claims directed to the following patentably distinct species of the claimed invention III: wherein the vector comprises:

A) SEQ ID NO:6,
B) SEQ ID NO:7
C) SEQ ID NO:89
D) SEQ ID NO:90, or
E) SEQ ID NO:91.

Each vector differs in its structure/sequence; therefore each represents patentably distinct subject matter.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, it is unclear if any of claims 52-55 are generic to these species. Applicant is required to identify which claim or claims is generic to the elected SEQ ID NO.

18. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

19. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark whose telephone number is (703) 605-1209. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
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Technology Center 1600
March 3, 2003

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